[BILLING CODE: 4140-01-P]

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Information on licensing, co-development research collaborations, and/or copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email

ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the patent application or inquiries about licensing and/or co-development should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Modified griffithsin tandemers for enhanced activity and reduced viral aggregation

Description of Technology:

Griffithsin (GRFT) is a lectin with potent antiviral properties that is capable of preventing and treating infections caused by a number of enveloped viruses (including HIV, SARS, HCV, HSV, and Japanese encephalitis) and is currently in clinical development as an anti-HIV microbicide. In addition to its broad antiviral activity, GRFT is stable at high temperature and at a broad pH range, displays low toxicity and immunogenicity, and is amenable to large-scale manufacturing. Native GRFT is a domain-swapped homodimer that binds to viral envelope glycoproteins and has displayed mid-picomolar activity in cell-based anti-HIV assays. This invention is directed to synthetic proteins that comprise two (or more) obligate monomers ("mGRFT") joined by an amino acid linker to form tandemers ("mGRFT tandemers"). Each obligate monomer is generated by the addition of Gly-Ser residues in the hinge region of wild-type GRFT. Two or more

obligate monomers are joined by an amino acid linker to form the mGRFT tandamers. The properties of the mGRFT tandemers can be modulated by the length of the amino acid linker and the number of obligate monomers co-joined. mGRFT tandemers exhibit gore potent anti-viral properties when compared against native GRFT and are equipotent against viruses that are both sensitive and resistant to naive GRFT. As such, potential uses of the invention tandemers include topical and intravenous therapy to treat HIV infection, particularly to treat HIV infections that are resistant to native GRFT.

Potential Commercial Applications:

- Broad-spectrum antiviral agent similar to wild type GRFT
- Potential activity against SARS CoV, MERS, Ebola, HCV and influenza

Value Proposition:

- Broad antiviral activity
- Stable at high temperature and at a broad pH range
- Displays low toxicity and immunogenicity.

Development Stage: In vivo/Lead Validation

Inventor(s): Barry R. O'Keefe (NCI), A. Wlodawer (NCI), T. Moulaei (NCI)

Publication(s):

- Moulaei T. et al., Griffithsin tandemers: flexible and potent lectin inhibitors of the human immunodeficiency virus. Retrovirology. 2015 Jan 23;12:6.

- A. Chatterjee et al.,Griffithsin and Carrageenan Combination To Target Herpes Simplex Virus 2 and Human Papillomavirus, Antimicrob Agents Chemother. 2015 Dec; 59(12): 7290–7298.

Intellectual Property:

HHS Reference No. E-034-2013/0–US–01

PCT Application No. PCT/US2014/040992 (HHS Reference No. E-034-2013 /0-US-01) filed June 5, 2013 entitled “Modified griffithsin tandemers for enhanced activity and reduced viral aggregation“

Licensing and Collaborative/Co-Development Research Opportunity:

Researchers at the NCI seek licensees and/or co-development partners for the commercialization of Griffithsin and Griffithsin tandemers, specifically, additional studies on stability, toxicity, immunogenicity, and large-scale production.

Dated: February 1, 2016.

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John D. Hewes, Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute

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